IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA USA, INC. and CIPLA LTD., Defendants.	Civil Action No. _____

COMPLAINT

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") of Abbreviated New Drug Application ("ANDA") No. 219000 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product prior to the expiration of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"), 10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent"). Collectively, the '712 patent, '476 patent, '509 patent, '510 patent, '156 patent, '808

patent, '512 patent, '447 patent, '888 patent, '889 patent, '637 patent, and '643 patent are referred to herein as the "Patents-in-Suit."

PARTIES

Teva

2. Plaintiff Teva is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

Cipla

4. On information and belief, Defendant Cipla Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400 013, Maharashtra, India. On information and belief, Cipla Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

5. On information and belief, Defendant Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Ltd., and is controlled and dominated by Cipla Ltd. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

6. On information and belief, Cipla Ltd., acting in concert with Cipla USA, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Cipla Ltd., acting in concert with Cipla USA, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

7. On information and belief, Cipla knows and intends that upon approval of Cipla's ANDA, Cipla will manufacture and directly or indirectly market, sell, and distribute Cipla's Beclomethasone Dipropionate Inhalation Aerosol, 40 mcg ("Cipla's ANDA Product") throughout the United States, including in New Jersey.

8. On information and belief, Cipla Ltd. and Cipla USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Cipla's ANDA Product at issue.

9. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Ltd. and Cipla USA, Inc. will act in concert to market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

10. On information and belief, following any FDA approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, and sell Cipla's ANDA Product throughout the United States and within New Jersey.

11. On information and belief, following any FDA approval of Cipla's ANDA, Cipla knows and intends that Cipla's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

JURISDICTION

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); 28 U.S.C. §§ 2201 and 2202.

14. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Ltd. and Cipla USA, Inc.

15. This Court has personal jurisdiction over Cipla USA, Inc. because, among other things, Cipla USA, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Cipla USA, Inc. is a company with a principal place of business in New Jersey. On information and belief, Cipla USA, Inc. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

16. On information and belief, Cipla USA, Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from Cipla Ltd.

17. On information and belief, Cipla USA, Inc., acting as the agent of Cipla Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Cipla Ltd. or for which Cipla is the named applicant on approved ANDAs.

18. This Court has personal jurisdiction over Cipla Ltd. because, among other things, Cipla Ltd. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cipla Ltd. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

19. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because, among other things, on information and belief: (1) Cipla USA, Inc. and Cipla Ltd. acted in concert to file Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) Cipla USA, Inc. and Cipla Ltd., acting in concert and/or as agents of one another, will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, upon approval of Cipla's ANDA, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir.

2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

20. In addition, this Court has personal jurisdiction over Cipla USA, Inc. and Cipla Ltd. because Cipla USA, Inc. and Cipla Ltd. regularly (1) engage in patent litigation concerning FDA approved branded drug products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Teva Branded Pharmaceutical Products R&D, Inc. & Norton (Waterford) Ltd. v. Cipla Ltd.*, Civil Action No. 20-14890 (JXN)(MAH) (D.N.J.); *Par Pharmaceutical, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-1150 (MCA)(JBC) (D.N.J.); *Fennec Pharmaceuticals, Inc., et al v. Cipla Ltd. & Cipla USA, Inc.*, Civil Action No. 23-123 (JKS)(MAH) (D.N.J.); *Celgene Corp. v. Cipla Ltd.,* Civil Action No. 19-14731 (SDW)(LDW) (D.N.J.); *Cubist Pharm. LLC v. Cipla USA, Inc. & Cipla Ltd.*, Civil Action No. 19-12920 (BRM)(ZNQ) (D.N.J.).

21. For the above reasons, it would not be unfair or unreasonable for Cipla USA, Inc. and/or Cipla Ltd. to litigate this action in this District, and the Court has personal jurisdiction over them here.

VENUE

22. Plaintiffs incorporate each of the proceeding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this district for Cipla USA, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Cipla USA, Inc. is a company with a principal place of business in New Jersey and is subject to personal jurisdiction in this judicial district.

24. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Cipla Ltd., at least because, on information and belief, Cipla Ltd. is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

BACKGROUND

25. Teva is the holder of New Drug Application ("NDA") No. 207921 for Qvar RediHaler® 40 mcg (beclomethasone dipropionate, 40 mcg) Inhalation Aerosol. Teva's Qvar RediHaler® inhaler is approved by FDA for maintenance treatment of asthma as prophylactic therapy in adults and pediatric patients 4 years of age and older.

The '712 Patent

26. The '712 patent, entitled "Metered-Dose Inhaler" (Exhibit A), duly and legally issued on March 13, 2012.

27. Norton is the owner and assignee of the '712 patent.

28. The '712 patent is listed in connection with the Qvar RediHaler® in the Orange Book.

29. Claim 1 of the '712 patent claims:

> A dose counter for a metered-dose inhaler, the counter comprising:
>
> an actuator;
>
> a rotary gear;
>
> a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator,

the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;

a pawl to prevent reverse rotation of the rotary gear; and

a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;

wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear,

the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

30. Claim 18 of the ’712 patent claims:

The use of a dose counter for preventing miscounting in a metered dose inhaler, the dose counter comprising:

an actuator;

a rotary gear;

a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator,

the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;

a pawl to prevent reverse rotation of the rotary gear; and

a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;

wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear,

the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

31. Claim 19 of the ’712 patent claims:

The use of a dose counter for preventing undercounting in a metered dose inhaler, the dose counter comprising:

an actuator;

a rotary gear;

a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator,

the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;

a pawl to prevent reverse rotation of the rotary gear; and

a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;

wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear,

the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

The ’476 Patent

32. The ’476 patent, entitled “Inhaler” (Exhibit B), duly and legally issued on January 13, 2015.

33. Norton is the owner and assignee of the ’476 patent.

34. The ’476 patent is listed in connection with Qvar RediHaler® in the Orange Book.

35. Claim 1 of the ’476 patent claims:

An inhaler for delivering medicament to a patient, the inhaler comprising

a housing for holding the medicament and having an air inlet means and a medicament delivery port which together define an air flow path into which the medicament is dispensed,

wherein the air inlet means comprises an array of elongate apertures formed in the housing,

wherein long sides of adjacent apertures face each other, and each aperture being provided with a respective different opening in an outer surface of the housing, and

wherein the opening of each aperture extends in two different planes such that, if at least a part of the opening is covered in one of two different planes during inhalation by the patient, a void space is created between a cover and the aperture so as to provide an air flow path through the void space to the at least one aperture,

wherein a raised formation is provided in the outer surface of the housing between adjacent apertures to either limit or prevent a covered opening.

36. Claim 17 of the ’476 patent claims:

A metered-dose inhaler for delivering medicament to a patient, the inhaler comprising

a housing for holding the medicament and having an air inlet means and a medicament delivery port which together define an air flow path into which the medicament is dispensed,

wherein the housing comprises an elongate body and the air inlet means is provided in an end face of the elongate body,

wherein the air inlet means comprises an array of elongate apertures formed in the housing, long sides of adjacent apertures facing each other, and each aperture being

provided with a respective different opening in an outer surface of the housing,

wherein each aperture is provided in a respective different recess in the outer surface of the housing, which recess defines the opening of the aperture,

and wherein the opening of each aperture in the outer surface of the housing extends in two different planes defining an angle of at least 45 degrees to each other, such that, if at least a part of the opening is covered in one of the two different planes during inhalation by the patient, a void space is created between the patient and the aperture so as to provide an air flow path through the void space to the at least one aperture.

The '509 Patent

37. The '509 patent, entitled "Dose Counter for Inhaler Having a Bore and Shaft Arrangement" (Exhibit C), duly and legally issued on July 17, 2018.

38. Norton is the owner and assignee of the '509 patent.

39. The '509 patent is listed in connection with Qvar RediHaler® in the Orange Book.

40. Claim 1 of the '509 Patent claims:

A dose counter for an inhaler, the dose counter having a display tape arranged to be incrementally driven from a tape stock bobbin onto an incremental tape take-up drive shaft, the bobbin having an internal bore supported by and for rotation about a support shaft, at least one of the bore and the support shaft having a radially extending protrusion having a leading portion edge, a trailing portion edge, wherein at least one of the leading portion edge and the trailing portion edge are tapered, and a friction edge between the leading portion edge and the trailing portion edge, wherein the friction edge is substantially parallel to a longitudinal axis of the support shaft and the leading portion edge and trailing portion edge are not parallel to the longitudinal axis of the support shaft, and the friction edge is resiliently biased into frictional engagement with the other of the bore and support shaft with longitudinally extending mutual frictional interaction and wherein the friction edge extends further in a longitudinal direction than the protrusion extends radially.

The '510 Patent

41. The '510 patent, entitled "Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof" (Exhibit D), duly and legally issued on July 17, 2018.

42. Norton is the owner and assignee of the '510 patent.

43. The '510 patent is listed in connection with Qvar RediHaler® in the Orange Book.

44. Claim 1 of the '510 patent claims:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
>
> > a tape system having a main elongate tape structure, dosing Indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, and priming indicia located on the main elongate tape structure, the priming indicia being located between the dosing indicia and a first end of the main elongate tape structure and visible in the dose counter viewing window before priming before first use, and
> >
> > wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

45. Claim 10 of the '510 patent claims:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
>
> > a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape

structure, and a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, wherein the tape size marker is positioned between a first end of the main elongate tape structure and the tape positioning indicia,

wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the tape is around both the stock bobbin and tape reel shaft and a portion of the main elongate tape structure between the tape positioning indicia and the dosing indicia is visible in the dose counter viewing window before priming before first use.

46. Claim 20 of the ’510 patent claims:

An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:

a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure so as to be visible in the dose counter viewing window before priming before first use, and priming indicia located on the main elongate tape structure, the priming indicia being located between the tape positioning indicia and the dosing indicia,

wherein a first end of the main elongate tape structure is attached to a stock bobbin and a second end of the main elongate tape structure is fixed to a tape reel shaft, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

The ’156 Patent

47. The ’156 patent, entitled “Dose Counter for Inhaler and Method of Counting Doses” (Exhibit E), duly and legally issued on October 2, 2018.

48. Norton is the owner and assignee of the ’156 patent.

49. The '156 patent is listed in connection with Qvar RediHaler® in the Orange Book.

50. Claim 1 of the '156 patent claims:

> A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
>
> a ratchet wheel having a plurality of circumferentially spaced teeth,
>
> an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
>
> a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
>
> a dosage indicator associated with the count pawl,
>
> wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
>
> wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,
>
> wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament

canister.

The '808 Patent

51. The '808 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit F), duly and legally issued on February 18, 2020.

52. Norton is the owner and assignee of the '808 patent.

53. The '808 patent is listed in connection with Qvar RediHaler® in the Orange Book.

54. Claim 1 of the '808 patent claims:

> A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

The '512 Patent

55. The '512 patent, entitled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator" (Exhibit G), duly and legally issued on June 30, 2020.

56. Norton is the owner and assignee of the '512 patent.

57. The '512 patent is listed in connection with Qvar RediHaler® in the Orange Book.

58. Claim 1 of the '512 patent claims:

> An inhaler for inhaling medicament, the inhaler having:
>
> A body for retaining a medicament canister; and
>
> a dose counter, the dose counter having a moveable actuator and a chassis mounted on the body;
>
> wherein one of the body and the chassis includes a plurality of apertures for receiving one or more pins on the other of

the body and the chassis,

wherein either the pins or the apertures on the chassis are positioned on different sides of the chassis for stabilizing the chassis on the body, and

wherein the chassis comprises at least one of a pin or aperture heat staked to a respective aperture or pin of the body to mount the chassis to the body.

The '447 Patent

59. The '447 patent, entitled "Breath Actuated Inhaler" (Exhibit H), duly and legally issued on October 6, 2020.

60. Norton is the owner and assignee of the '447 patent.

61. The '447 patent is listed in connection with Qvar RediHaler® in the Orange Book.

62. Claim 1 of the '447 patent claims:

A breath actuated metered dose inhaler comprising:

a canister fire system configured to provide a canister actuation force to fire a medicament containing canister in response to patient inhalation, the canister fire system comprising a pneumatic force holding unit and having:

a rest configuration in which a metering valve of the canister is in a refill configuration;

a prepared configuration in which a canister actuation force is retained by a difference in pressure between an enclosed volume within the pneumatic force holding unit and atmospheric pressure, and in which prepared configuration the canister fire system is actuatable by patient inhalation induced airflow;

and a fire configuration in which the metering valve is in a dose delivery position;

wherein, in the prepared configuration, the force retained by the pneumatic force holding unit reduces but by less than about 6% over a period of 5 minutes.

63. Claim 10 of the ’447 patent claims:

A breath actuated metered dose inhaler comprising:

> a canister fire system configured to provide a canister actuation force to fire a medicament containing canister in response to patient inhalation, the canister fire system comprising a pneumatic force holding unit and having:
>
> a rest configuration in which a metering valve of the canister is in a refill configuration;
>
> a prepared configuration in which a canister actuation force is retained by a difference in pressure between an enclosed volume within the pneumatic force holding unit and atmospheric pressure, and in which prepared configuration the canister fire system is actuatable by patient inhalation induced airflow;
>
> and a fire configuration in which the metering valve is in a dose delivery position;
>
> wherein, in the prepared configuration, the force retained by the pneumatic force holding unit reduces but by less than about 6% over a period of 5 minutes and wherein the pneumatic force holding unit further comprises a valve port comprising a relatively rigid valve seal surface configured to be sealably engaged by an elastomeric valve seal, wherein the relatively rigid valve seal surface has a surface roughness average (RA) of less than about 0.15 μm.

The ’888 Patent

64. The ’888 patent, entitled “Inhalers and Related Methods” (Exhibit I), duly and legally issued on July 26, 2022.

65. Norton is the owner and assignee of the ’888 patent.

66. The ’888 patent is listed in connection with Qvar RediHaler® in the Orange Book.

67. Claim 1 of the ’888 patent claims:

A breath actuated inhaler having

a drive adapted to drive a pressurized canister so as to retract a metering valve stem into the pressurized canister to fire the pressurized canister,

the pressurized canister comprising a metering chamber and an interior reservoir, and being adapted to move during operation between 1 and 4 mm between end positions of its length of travel relative to the valve stem,

the drive being arranged to apply a firing force of greater than 35 N and less than 60 N to the pressurized canister at a position of the pressurized canister relative to the valve stem at which the pressurized canister fires,

the breath actuated inhaler further having a metering valve spring and a dose counter with a dose counter biasing element that cooperate together with the drive to hold the pressurized canister in a ready-to-fire configuration in which the pressurized canister is displaced from the end positions and the metering chamber is isolated from the atmosphere and wherefrom, in response to air flow, the pressurized canister is movable to close communication between the metering chamber and the interior reservoir and to open communication between the metering chamber and the atmosphere, and

a vacuum chamber external to the metering chamber, wherein the metering valve spring and the dose counter biasing element combine with a vacuum force from the vacuum chamber to oppose a force from the drive when the pressurized canister is in the ready-to-fire configuration.

68. Claim 25 of the ’888 patent claims:

A breath actuated inhaler having

a drive adapted to drive a pressurized canister so as to retract a metering valve stem into the pressurized canister to fire the pressurized canister,

the pressurized canister comprising a metering chamber and an interior reservoir, and being adapted to move during operation between 1 and 4 mm between end positions of its length of travel relative to the valve stem,

the drive being arranged to apply a firing force of greater than 35 N and less than 60 N to the pressurized canister at a position of the pressurized canister relative to the valve stem

at which the pressurized canister fires,

the breath actuated inhaler further having a metering valve spring and a dose counter with a dose counter biasing element that cooperate together with the drive to hold the pressurized canister in a ready-to-fire configuration in which the pressurized canister is displaced from the end positions and the metering chamber is isolated from the atmosphere and wherefrom, in response to air flow, the pressurized canister is movable to close communication between the metering chamber and the interior reservoir and to open communication between the metering chamber and the atmosphere,

the breath actuated inhaler further having an actuator system for operating the drive, wherein the actuator system includes a vacuum chamber external to the metering chamber having a vacuum release system operable to permit the drive to drive movement of the pressurized canister relative to the valve stem, and the metering valve spring, a vacuum force from the vacuum chamber, and the dose counter biasing element combine to oppose a force from the drive when the pressurized canister is in the ready-to-fire configuration.

The ’889 Patent

69. The ’889 patent, entitled “Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator” (Exhibit J), duly and legally issued on July 26, 2022.

70. Norton is the owner and assignee of the ’889 patent.

71. The ’889 patent is listed in connection with Qvar RediHaler® in the Orange Book.

72. Claim 1 of the ’889 patent claims:

An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter

further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

The '637 Patent

73. The '637 patent, entitled "Inhalers and Related Methods" (Exhibit K), duly and legally issued on January 24, 2023.

74. Norton is the owner and assignee of the '637 patent.

75. The '637 patent is listed in connection with Qvar RediHaler® in the Orange Book.

76. Claim 1 of the '637 patent claims:

A breath actuated inhaler comprising:

a main body for accommodating a medicament reservoir,

a canister fire system including

a trigger; and

a biasing element for moving a canister to release a dose in response to air flow,

a cap housing,

an interior chamber defined by the main body and the cap housing, the canister fire system and canister being enclosed within the interior chamber, and

a lock system including helical threads having non-overlapping and distinct thread segments for providing rotational attachment of the cap housing to the main body and a first lock member that cooperates with a second lock member to achieve a snap lock between the cap housing and the main body when the cap housing is rotationally attached to the main body in a locked position,

wherein the thread segments are radially disposed about a central axis and arranged such that the thread segments are non-overlapping with respect to each other along the central

axis, and

wherein the first lock member is interposed between the thread segments.

77. Claim 28 of the ’637 patent claims:

A breath actuated inhaler comprising:

a main body for accommodating a medicament reservoir,

a canister fire system for moving a canister to release a dose in response to air flow,

a cap housing for enclosing the canister fire system and canister within an interior chamber defined by the main body and the cap housing, and in which the main body and the cap housing are formed of plastics material characterized in that a lock system is provided for locking the cap housing on the main body,

wherein the lock system includes:

helical threads having non-overlapping and distinct thread segments for providing rotational attachment of the cap housing on the main body; and

a first lock member that cooperates with a second lock member to achieve a snap lock between the cap housing and the main body when the cap housing is rotationally attached to the main body in a locked position,

wherein the thread segments are radially disposed about a central axis and arranged such that the thread segments are non-overlapping with respect to each other along the central axis, wherein the first lock member is interposed between the thread segments, and

wherein a release torque required to overcome the lock system is more than 1 Nm and lower than 4 Nm.

The ’643 Patent

78. The ’643 patent, entitled “Inhalers and Related Methods” (Exhibit L), duly and legally issued on February 21, 2023.

79. Norton is the owner and assignee of the ’643 patent.

80. The ’643 patent is listed in connection with Qvar RediHaler® in the Orange Book.

81. Claim 1 of the ’643 patent claims:

A method of metering inhalable substances, the method comprising:

> providing a medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;
>
> operating the medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber;
>
> following the time period, orienting the interior reservoir above the metering chamber to permit the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and
>
> administering, from the liquid replacement, 75% to 125% of labelled claim for a dose.

82. Claim 35 of the ’643 patent claims:

A method of metering an inhalable composition comprising:

> discharging a first metered dose from a medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, configured to permit flow between the valve stem and the interior reservoir;

upon discharge of the first metered dose, causing the valve stem to be in a retracted position for a time period of about 2 minutes to about 24 hours during which the metering chamber stays open and exposed to atmosphere to permit atmospheric air to enter the metering chamber;

at an end of the time period, orienting the interior reservoir above the metering chamber to replace the atmospheric air within the metering chamber with a replacement liquid; and

actuating the medicament inhaler to discharge a second metered dose having 75% to 125% of labelled claim for a dose from the replacement liquid.

83. Claim 36 of the ’643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the

atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and

administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,

wherein the respiratory disease includes one or more of asthma and COPD, and the one or more active ingredients include one or more of corticosteroid, beclomethasone dipropionate, and tiotropium bromide.

84. Claim 37 of the ’643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and

administering, from the liquid replacement, 75% to 125% of labelled claim for a dose, wherein the respiratory disease includes asthma, and the one or more active ingredients include corticosteroid.

85. Claim 38 of the ’643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and

administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,

wherein the respiratory disease includes asthma and the one or more active ingredients include beclomethasone dipropionate or tiotropium bromide.

86. Claim 39 of the ’643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and

administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,

wherein the respiratory disease includes COPD and the one or more active ingredients include corticosteroid.

87. Claim 40 of the ’643 patent claims:

A method of treating a respiratory disease or disorder by administering a therapeutically effective amount of one or more active ingredients, the method comprising:

providing a breath-actuated medicament inhaler having a metering valve with a metering chamber and a valve stem extending from the metering chamber to an interior reservoir of a canister, the valve stem defining a communication path between the metering chamber and the interior reservoir, the communication path including an opening configured to permit flow between a transfer space inside the valve stem and the interior reservoir;

operating the breath-actuated medicament inhaler to cause substances within the metering chamber to vaporise and the valve stem to be in a retracted position relative to the canister for a time period of about 2 minutes to about 24 hours such that atmospheric air enters the metering chamber, wherein operating the breath-actuated medicament inhaler includes inhaling through the breath-actuated medicament inhaler;

following the time period, resetting the inhaler to a reset configuration with a reset actuator to close communication between the metering chamber and atmosphere and open communication between the metering chamber and the interior reservoir;

while the inhaler is in the reset configuration, orienting the interior reservoir above the metering chamber to cause the atmospheric air within the metering chamber to be replaced with a liquid replacement from the interior reservoir; and administering, from the liquid replacement, 75% to 125% of labelled claim for a dose,

wherein the respiratory disease includes COPD and the one or more active ingredients include beclomethasone dipropionate or tiotropium bromide.

INFRINGEMENT BY CIPLA

88. By letter dated January 4, 2024 ("Cipla's Notice Letter"), Cipla notified Teva that it had filed Paragraph IV Certifications with respect to the Patents-in-Suit and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit. On information and belief, Cipla's ANDA contains Paragraph IV Certifications asserting that Patents-

in-Suit will not be infringed by the manufacture, use, offer for sale, sale, or importation of Cipla's ANDA Product, or alternatively, that the Patents-in-Suit are invalid.

89. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit.

90. In Cipla's Notice Letter, Cipla stated that the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

91. In Cipla's Notice Letter, Cipla stated that the active ingredient of Cipla's ANDA Product is beclomethasone dipropionate.

92. In Cipla's Notice Letter, Cipla stated that the proposed dosage strength of Cipla's ANDA Product is 40 mcg per actuation.

93. In Cipla's Notice Letter, Cipla stated that the established name of the proposed drug product that is the subject of Cipla's ANDA is "Beclomethasone Dipropionate HFA Inhalation Aerosol, 40 mcg."

94. Cipla's Notice Letter purported to provide Teva with an Offer of Confidential Access ("OCA") to portions of Cipla's ANDA. That offer, however, was subject to various unreasonably restrictive conditions.

95. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Offer of Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Cipla's ANDA and any Drug Master File referred to therein, and Cipla refused to produce samples of Cipla's ANDA Product and other internal documents and material relevant to infringement.

96. On January 16, 2024, Teva's counsel sent Cipla's counsel a letter requesting documents and identifying various unreasonably restrictive terms in Cipla's OCA, including but not limited to restrictions on the conduct of Teva's outside counsel in future post-grant and FDA proceedings, prohibitions on providing information to outside consultants, choice of law, and limitations on the scope of documents Cipla would provide to Teva.

97. On January 25, 2024, Cipla's counsel sent Teva's counsel an email refusing to provide the documents and materials requested by Teva and necessary to evaluate Cipla's ANDA Products for infringement.

98. On February 8, 2024, Teva's counsel reiterated to Cipla's counsel via email Teva's need for specific materials to evaluate infringement and proposed reasonable terms for confidentiality protections.

99. Teva's counsel has not received a response to its February 8, 2024 email.

100. Cipla's Notice Letter appends a document titled "Detailed Statement" asserting that the commercial manufacture, use, or sale of Cipla's ANDA Product will not infringe any of the Patents-in-Suit. However, Cipla's Notice Letter and "Detailed Statement" do not provide information regarding Cipla's ANDA Product sufficient to evaluate Cipla's assertions of noninfringement. Indeed, Cipla's Notice Letter and "Detailed Statement" fail to provide any information regarding Cipla's ANDA Product beyond the unsupported and unexplained assertions by Cipla's attorneys that Cipla's ANDA Product do not meet certain limitations of each of the Patents-in-Suit.

101. This action is being commenced before the expiration of forty-five days from the date of the receipt of Cipla's Notice Letter.

COUNT 1 – INFRINGEMENT BY CIPLA
OF THE '712 PATENT UNDER 35 U.S.C. § 271(e)(2)

102. Plaintiffs incorporate each of the preceding paragraphs 1–97 as if fully set forth herein.

103. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '712 patent was an act of infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A).

104. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above, either literally or under the doctrine of equivalents.

105. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

106. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above.

107. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '712 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

108. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '712 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing

use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '712 patent after approval of Cipla's ANDA.

109. The foregoing actions by Cipla constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

110. On information and belief, Cipla has acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

111. Unless Cipla is enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 2 – INFRINGEMENT BY CIPLA OF THE '476 PATENT UNDER 35 U.S.C. § 271(e)(2)

112. Plaintiffs incorporate each of the preceding paragraphs 1–107 as if fully set forth herein.

113. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '476 patent was an act of infringement of the '476 patent under 35 U.S.C. § 271(e)(2)(A).

114. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 17 of the '476 patent, recited above, either literally or under the doctrine of equivalents.

115. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

116. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 17 of the '476 patent, recited above.

117. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '476 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

118. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '476 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '476 patent after approval of Cipla's ANDA.

119. The foregoing actions by Cipla constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and contribution to the infringement by others of the '476 patent.

120. On information and belief, Cipla has acted with full knowledge of the '476 patent and without a reasonable basis for believing that it would not be liable for infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent.

121. Unless Cipla is enjoined from infringing the ’476 patent, actively inducing infringement of the ’476 patent, and contributing to the infringement by others of the ’476 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 3 – INFRINGEMENT BY CIPLA OF THE ’509 PATENT UNDER 35 U.S.C. § 271(e)(2)

122. Plaintiffs incorporate each of the preceding paragraphs 1–117 as if fully set forth herein.

123. Cipla’s submission of Cipla’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s ANDA Product prior to the expiration of the ’509 patent was an act of infringement of the ’509 patent under 35 U.S.C. § 271(e)(2)(A).

124. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product would infringe at least claim 1 of the ’509 patent, recited above, either literally or under the doctrine of equivalents.

125. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product immediately and imminently upon FDA approval of Cipla’s ANDA.

126. On information and belief, the use of Cipla’s ANDA Product in accordance with and as directed by Cipla’s proposed labeling for that product would infringe at least claim 1 of the ’509 patent, recited above.

127. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the ’509 patent when Cipla’s ANDA is approved, and plans and intends to, and will, do so after approval.

128. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '509 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '509 patent after approval of Cipla's ANDA.

129. The foregoing actions by Cipla constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

130. On information and belief, Cipla has acted with full knowledge of the '509 patent and without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

131. Unless Cipla is enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 4 – INFRINGEMENT BY CIPLA
OF THE '510 PATENT UNDER 35 U.S.C. § 271(e)(2)

132. Plaintiffs incorporate each of the preceding paragraphs 1–127 as if fully set forth herein.

133. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '510 patent was an act of infringement of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

134. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, either literally or under the doctrine of equivalents.

135. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

136. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above.

137. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '510 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

138. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '510 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '510 patent after approval of Cipla's ANDA.

139. The foregoing actions by Cipla constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

140. On information and belief, Cipla has acted with full knowledge of the '510 patent and without a reasonable basis for believing that it would not be liable for infringing the

'510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

141. Unless Cipla is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 5 – INFRINGEMENT BY CIPLA OF THE '156 PATENT UNDER 35 U.S.C. § 271(e)(2)

142. Plaintiffs incorporate each of the preceding paragraphs 1–137 as if fully set forth herein.

143. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '156 patent was an act of infringement of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

144. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

145. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

146. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '156 patent, recited above.

147. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '156 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

148. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '156 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '156 patent after approval of Cipla's ANDA.

149. The foregoing actions by Cipla constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

150. On information and belief, Cipla has acted with full knowledge of the '156 patent and without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

151. Unless Cipla is enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 6 – INFRINGEMENT BY CIPLA
OF THE '808 PATENT UNDER 35 U.S.C. § 271(e)(2)

152. Plaintiffs incorporate each of the preceding paragraphs 1–147 as if fully set forth herein.

153. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's

ANDA Product prior to the expiration of the '808 patent was an act of infringement of the '808 patent under 35 U.S.C. § 271(e)(2)(A).

154. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

155. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

156. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '808 patent, recited above.

157. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '808 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

158. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '808 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '808 patent after approval of Cipla's ANDA.

159. The foregoing actions by Cipla constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

160. On information and belief, Cipla has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

161. Unless Cipla is enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 7 – INFRINGEMENT BY CIPLA OF THE '512 PATENT UNDER 35 U.S.C. § 271(e)(2)

162. Plaintiffs incorporate each of the preceding paragraphs 1–157 as if fully set forth herein.

163. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '512 patent was an act of infringement of the '512 patent under 35 U.S.C. § 271(e)(2)(A).

164. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '512 patent, recited above, either literally or under the doctrine of equivalents.

165. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

166. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '512 patent, recited above.

167. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the ’512 patent when Cipla’s ANDA is approved, and plans and intends to, and will, do so after approval.

168. On information and belief, Cipla knows that Cipla’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’512 patent and that Cipla’s ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the ’512 patent after approval of Cipla’s ANDA.

169. The foregoing actions by Cipla constitute and/or will constitute infringement of the ’512 patent, active inducement of infringement of the ’512 patent, and contribution to the infringement by others of the ’512 patent.

170. On information and belief, Cipla has acted with full knowledge of the ’512 patent and without a reasonable basis for believing that it would not be liable for infringing the ’512 patent, actively inducing infringement of the ’512 patent, and contributing to the infringement by others of the ’512 patent.

171. Unless Cipla is enjoined from infringing the ’512 patent, actively inducing infringement of the ’512 patent, and contributing to the infringement by others of the ’512 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 8 – INFRINGEMENT BY CIPLA
OF THE ’447 PATENT UNDER 35 U.S.C. § 271(e)(2)

172. Plaintiffs incorporate each of the preceding paragraphs 1–167 as if fully set forth herein.

173. Cipla’s submission of Cipla’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s

ANDA Product prior to the expiration of the '447 patent was an act of infringement of the '447 patent under 35 U.S.C. § 271(e)(2)(A).

174. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 10 of the '447 patent, recited above, either literally or under the doctrine of equivalents.

175. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

176. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 10 of the '447 patent, recited above.

177. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '447 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

178. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '447 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '447 patent after approval of Cipla's ANDA.

179. The foregoing actions by Cipla constitute and/or will constitute infringement of the '447 patent, active inducement of infringement of the '447 patent, and contribution to the infringement by others of the '447 patent.

180. On information and belief, Cipla has acted with full knowledge of the '447 patent and without a reasonable basis for believing that it would not be liable for infringing the '447 patent, actively inducing infringement of the '447 patent, and contributing to the infringement by others of the '447 patent.

181. Unless Cipla is enjoined from infringing the '447 patent, actively inducing infringement of the '447 patent, and contributing to the infringement by others of the '447 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 9 – INFRINGEMENT BY CIPLA OF THE '888 PATENT UNDER 35 U.S.C. § 271(e)(2)

182. Plaintiffs incorporate each of the preceding paragraphs 1–177 as if fully set forth herein.

183. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '888 patent was an act of infringement of the '888 patent under 35 U.S.C. § 271(e)(2)(A).

184. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 25 of the '888 patent, recited above, either literally or under the doctrine of equivalents.

185. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

186. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 25 of the '888 patent, recited above.

187. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '888 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

188. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '888 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '888 patent after approval of Cipla's ANDA.

189. The foregoing actions by Cipla constitute and/or will constitute infringement of the '888 patent, active inducement of infringement of the '888 patent, and contribution to the infringement by others of the '888 patent.

190. On information and belief, Cipla has acted with full knowledge of the '888 patent and without a reasonable basis for believing that it would not be liable for infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent.

191. Unless Cipla is enjoined from infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 10 – INFRINGEMENT BY CIPLA
OF THE '889 PATENT UNDER 35 U.S.C. § 271(e)(2)

192. Plaintiffs incorporate each of the preceding paragraphs 1–187 as if fully set forth herein.

193. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '889 patent was an act of infringement of the '889 patent under 35 U.S.C. § 271(e)(2)(A).

194. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '889 patent, recited above, either literally or under the doctrine of equivalents.

195. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

196. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '889 patent, recited above.

197. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '889 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

198. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '889 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing

use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '889 patent after approval of Cipla's ANDA.

199. The foregoing actions by Cipla constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

200. On information and belief, Cipla has acted with full knowledge of the '889 patent and without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

201. Unless Cipla is enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 11 – INFRINGEMENT BY CIPLA OF THE '637 PATENT UNDER 35 U.S.C. § 271(e)(2)

202. Plaintiffs incorporate each of the preceding paragraphs 1–197 as if fully set forth herein.

203. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '637 patent was an act of infringement of the '637 patent under 35 U.S.C. § 271(e)(2)(A).

204. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 28 of the '637 patent, recited above, either literally or under the doctrine of equivalents.

205. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

206. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 28 of the '637 patent, recited above.

207. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '637 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

208. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '637 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '637 patent after approval of Cipla's ANDA.

209. The foregoing actions by Cipla constitute and/or will constitute infringement of the '637 patent, active inducement of infringement of the '637 patent, and contribution to the infringement by others of the '637 patent.

210. On information and belief, Cipla has acted with full knowledge of the '637 patent and without a reasonable basis for believing that it would not be liable for infringing the '637 patent, actively inducing infringement of the '637 patent, and contributing to the infringement by others of the '637 patent.

211. Unless Cipla is enjoined from infringing the '637 patent, actively inducing infringement of the '637 patent, and contributing to the infringement by others of the '637 patent,

Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 12 – INFRINGEMENT BY CIPLA
OF THE '643 PATENT UNDER 35 U.S.C. § 271(e)(2)

212. Plaintiffs incorporate each of the preceding paragraphs 1–207 as if fully set forth herein.

213. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '643 patent was an act of infringement of the '643 patent under 35 U.S.C. § 271(e)(2)(A).

214. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above, either literally or under the doctrine of equivalents.

215. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product immediately and imminently upon FDA approval of Cipla's ANDA.

216. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above.

217. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '643 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

218. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling is especially made or adapted for use in infringing the '643 patent and that

Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '643 patent after approval of Cipla's ANDA.

219. The foregoing actions by Cipla constitute and/or will constitute infringement of the '643 patent, active inducement of infringement of the '643 patent, and contribution to the infringement by others of the '643 patent.

220. On information and belief, Cipla has acted with full knowledge of the '643 patent and without a reasonable basis for believing that it would not be liable for infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent.

221. Unless Cipla is enjoined from infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 13 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '712 PATENT

222. Plaintiffs incorporate each of the preceding paragraphs 1–217 as if fully set forth herein.

223. Cipla has knowledge of the '712 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

224. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above, either literally or under the doctrine of equivalents.

225. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

226. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above.

227. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '712 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

228. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '712 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '712 patent after approval of Cipla's ANDA.

229. The foregoing actions by Cipla constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

230. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

231. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according

to Cipla's ANDA will infringe at least claims 1, 18, and/or 19 of the '712 patent, recited above, and whether said claims of the '712 patent are valid.

232. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '712 patent and that the claims of the '712 patent are valid.

233. Cipla should be enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 14 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '476 PATENT

234. Plaintiffs incorporate each of the preceding paragraphs 1–229 as if fully set forth herein.

235. Cipla has knowledge of the '476 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

236. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 17 of the '476 patent, recited above, either literally or under the doctrine of equivalents.

237. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

238. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 17 of the '476 patent, recited above.

239. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '476 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

240. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '476 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '476 patent after approval of Cipla's ANDA.

241. The foregoing actions by Cipla constitute and/or will constitute infringement of the '476 patent, active inducement of infringement of the '476 patent, and contribution to the infringement by others of the '476 patent.

242. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent.

243. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1 and/or 17 of the '476 patent, recited above, and whether said claims of the '476 patent are valid.

244. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '476 patent and that the claims of the '476 patent are valid.

245. Cipla should be enjoined from infringing the '476 patent, actively inducing infringement of the '476 patent, and contributing to the infringement by others of the '476 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 15 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '509 PATENT

246. Plaintiffs incorporate each of the preceding paragraphs 1–241 as if fully set forth herein.

247. Cipla has knowledge of the '509 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

248. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '509 patent, recited above, either literally or under the doctrine of equivalents.

249. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

250. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '509 patent, recited above.

251. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '509 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

252. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '509 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '509 patent after approval of Cipla's ANDA.

253. The foregoing actions by Cipla constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

254. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

255. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '509 patent, recited above, and whether said claim or claims of the '509 patent are valid.

256. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '509 patent and that the claims of the '509 patent are valid.

257. Cipla should be enjoined from infringing the ’509 patent, actively inducing infringement of the ’509 patent, and contributing to the infringement by others of the ’509 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 16 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE ’510 PATENT

258. Plaintiffs incorporate each of the preceding paragraphs 1–253 as if fully set forth herein.

259. Cipla has knowledge of the ’510 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

260. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product would infringe at least claims 1, 10, and/or 20 of the ’510 patent, recited above, either literally or under the doctrine of equivalents.

261. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product with its proposed labeling upon FDA approval of Cipla’s ANDA.

262. On information and belief, the use of Cipla’s ANDA Product in accordance with and as directed by Cipla’s proposed labeling for that product would infringe at least claims 1, 10, and/or 20 of the ’510 patent, recited above.

263. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the ’510 patent when Cipla’s ANDA is approved, and plans and intends to, and will, do so after approval.

264. On information and belief, Cipla knows that Cipla’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’510 patent and that

Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '510 patent after approval of Cipla's ANDA.

265. The foregoing actions by Cipla constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

266. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

267. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1, 10, and/or 20 of the '510 patent, recited above, and whether said claims of the '510 patent are valid.

268. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '510 patent and that the claims of the '510 patent are valid.

269. Cipla should be enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 17 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '156 PATENT

270. Plaintiffs incorporate each of the preceding paragraphs 1–265 as if fully set forth herein.

271. Cipla has knowledge of the '156 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

272. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '156 patent, recited above, either literally or under the doctrine of equivalents.

273. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

274. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '156 patent, recited above.

275. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '156 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

276. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '156 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '156 patent after approval of Cipla's ANDA.

277. The foregoing actions by Cipla constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

278. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

279. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '156 patent, recited above, and whether said claim or claims of the '156 patent are valid.

280. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '156 patent and that the claims of the '156 patent are valid.

281. Cipla should be enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 18 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '808 PATENT

282. Plaintiffs incorporate each of the preceding paragraphs 1–277 as if fully set forth herein.

283. Cipla has knowledge of the '808 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

284. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '808 patent, recited above, either literally or under the doctrine of equivalents.

285. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

286. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '808 patent, recited above.

287. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '808 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

288. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '808 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '808 patent after approval of Cipla's ANDA.

289. The foregoing actions by Cipla constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

290. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

291. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '808 patent, recited above, and whether said claim or claims of the '808 patent are valid.

292. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '808 patent and that the claims of the '808 patent are valid.

293. Cipla should be enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 19 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '512 PATENT

294. Plaintiffs incorporate each of the preceding paragraphs 1–289 as if fully set forth herein.

295. Cipla has knowledge of the '512 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

296. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '512 patent, recited above, either literally or under the doctrine of equivalents.

297. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

298. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claim 1 of the '512 patent, recited above.

299. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '512 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

300. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '512 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '512 patent after approval of Cipla's ANDA.

301. The foregoing actions by Cipla constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

302. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

303. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claim 1 of the '512 patent, recited above, and whether said claim or claims of the '512 patent are valid.

304. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '512 patent and that the claims of the '512 patent are valid.

305. Cipla should be enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 20 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '447 PATENT

306. Plaintiffs incorporate each of the preceding paragraphs 1–301 as if fully set forth herein.

307. Cipla has knowledge of the '447 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

308. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 10 of the '447 patent, recited above, either literally or under the doctrine of equivalents.

309. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

310. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 10 of the '447 patent, recited above.

311. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '447 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

312. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '447 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '447 patent after approval of Cipla's ANDA.

313. The foregoing actions by Cipla constitute and/or will constitute infringement of the '447 patent, active inducement of infringement of the '447 patent, and contribution to the infringement by others of the '447 patent.

314. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '447 patent, actively inducing infringement of the '447 patent, and contributing to the infringement by others of the '447 patent.

315. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1 and/or 10 of the '447 patent, recited above, and whether said claims of the '447 patent are valid.

316. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '447 patent and that the claims of the '447 patent are valid.

317. Cipla should be enjoined from infringing the '447 patent, actively inducing infringement of the '447 patent, and contributing to the infringement by others of the '447 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 21 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '888 PATENT

318. Plaintiffs incorporate each of the preceding paragraphs 1–313 as if fully set forth herein.

319. Cipla has knowledge of the '888 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

320. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claims 1 and/or 25 of the '888 patent, recited above, either literally or under the doctrine of equivalents.

321. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

322. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 25 of the '888 patent, recited above.

323. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '888 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

324. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '888 patent and that

Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '888 patent after approval of Cipla's ANDA.

325. The foregoing actions by Cipla constitute and/or will constitute infringement of the '888 patent, active inducement of infringement of the '888 patent, and contribution to the infringement by others of the '888 patent.

326. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent.

327. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1 and/or 25 of the '888 patent, recited above, and whether said claims of the '888 patent are valid.

328. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '888 patent and that the claims of the '888 patent are valid.

329. Cipla should be enjoined from infringing the '888 patent, actively inducing infringement of the '888 patent, and contributing to the infringement by others of the '888 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 22 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE '889 PATENT

330. Plaintiffs incorporate each of the preceding paragraphs 1–325 as if fully set forth herein.

331. Cipla has knowledge of the '889 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

332. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '889 patent, recited above, either literally or under the doctrine of equivalents.

333. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

334. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 of the '889 patent, recited above.

335. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '889 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

336. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '889 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '889 patent after approval of Cipla's ANDA.

337. The foregoing actions by Cipla constitute and/or will constitute infringement of the ’889 patent, active inducement of infringement of the ’889 patent, and contribution to the infringement by others of the ’889 patent.

338. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the ’889 patent, actively inducing infringement of the ’889 patent, and contributing to the infringement by others of the ’889 patent.

339. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla’s manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product with its proposed labeling according to Cipla’s ANDA will infringe at least claim 1 of the ’889 patent, recited above, and whether said claim or claims of the ’889 patent are valid.

340. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’889 patent and that the claims of the ’889 patent are valid.

341. Cipla should be enjoined from infringing the ’889 patent, actively inducing infringement of the ’889 patent, and contributing to the infringement by others of the ’889 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 23 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE ’637 PATENT

342. Plaintiffs incorporate each of the preceding paragraphs 1–337 as if fully set forth herein.

343. Cipla has knowledge of the ’637 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

344. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe of at least claims 1 and/or 28 of the '637 patent, recited above, either literally or under the doctrine of equivalents.

345. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

346. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1 and/or 28 of the '637 patent, recited above.

347. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '637 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

348. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '637 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '637 patent after approval of Cipla's ANDA.

349. The foregoing actions by Cipla constitute and/or will constitute infringement of the '637 patent, active inducement of infringement of the '637 patent, and contribution to the infringement by others of the '637 patent.

350. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the ’637 patent, actively inducing infringement of the ’637 patent, and contributing to the infringement by others of the ’637 patent.

351. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla’s manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product with its proposed labeling according to Cipla’s ANDA will infringe at least claims 1 and/or 28 of the ’637 patent, recited above, and whether said claim or claims of the ’637 patent are valid.

352. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla’s ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the ’637 patent and that the claims of the ’637 patent are valid.

353. Cipla should be enjoined from infringing the ’637 patent, actively inducing infringement of the ’637 patent, and contributing to the infringement by others of the ’637 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT 24 – DECLARATORY JUDGMENT OF INFRINGEMENT BY CIPLA OF THE ’643 PATENT

354. Plaintiffs incorporate each of the preceding paragraphs 1–349 as if fully set forth herein.

355. Cipla has knowledge of the ’643 patent as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

356. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla’s ANDA Product would infringe at least

claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above, either literally or under the doctrine of equivalents.

357. On information and belief, Cipla will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product with its proposed labeling upon FDA approval of Cipla's ANDA.

358. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for that product would infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above.

359. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '643 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval.

360. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '643 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '643 patent after approval of Cipla's ANDA.

361. The foregoing actions by Cipla constitute and/or will constitute infringement of the '643 patent, active inducement of infringement of the '643 patent, and contribution to the infringement by others of the '643 patent.

362. On information and belief, Cipla has acted without a reasonable basis for believing that it would not be liable for infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent.

363. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Cipla regarding whether Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product with its proposed labeling according to Cipla's ANDA will infringe at least claims 1, 35, 36, 37, 38, 39, and/or 40 of the '643 patent, recited above, and whether said claims of the '643 patent are valid.

364. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of Cipla's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '643 patent and that the claims of the '643 patent are valid.

365. Cipla should be enjoined from infringing the '643 patent, actively inducing infringement of the '643 patent, and contributing to the infringement by others of the '643 patent; otherwise Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Cipla has infringed, will infringe, and will induce and contribute to infringement of each of the Patents-in-Suit

(b) A judgment that the Patents-in-Suit are valid and enforceable;

(c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Cipla to make, use, offer for sale, sell, market, distribute, or import Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Cipla, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Cipla's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit;

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Cipla engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Cipla's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and

additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

(g) A judgment that the infringement has been willful and an enhancement of damages;

(h) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(i) An award of Plaintiffs' costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Dated: February 16, 2024

Liza M. Walsh
Selina M. Ellis
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

OF COUNSEL:
David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue, S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

Local Rule 11.2 Certification

Pursuant to Local Civil Rule 11.2, we hereby certify that the matter in controversy in this action is related to the following actions: *Teva Branded Pharmaceutical Products R&D, Inc., et al., v. Cipla Ltd.*, No. 2023-2241, which proceeded to final judgment in the District of New Jersey and is now pending before the United States Court of Appeals for the Federal Circuit, which involved the same parties and in which Plaintiffs asserted the '509, '510, '156, and '808 patents against Defendant; *Teva Branded Pharmaceutical Products R&D, Inc., et al., v. Amneal Pharmaceuticals of New York, LLC, et al.*, 2:23-cv-20964 pending before the United States District Court for the District of New Jersey, in which the '712 and '808 patents have been asserted against defendants all believed to be unrelated to the Defendants named herein.

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

Dated: February 16, 2024

Liza M. Walsh
Selina M. Ellis
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

OF COUNSEL:
David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

WALSH PIZZI O'REILLY FALANGA LLP

s/ Liza M. Walsh

Dated: February 16, 2024

Liza M. Walsh
Selina M. Ellis
WALSH PIZZI O'REILLY FALANGA LLP
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.

OF COUNSEL:
David I. Berl
Benjamin M. Greenblum
Elise M. Baumgarten
Kathryn S. Kayali
Ben Picozzi
Ricardo Leyva
Richard Hildreth III
WILLIAMS & CONNOLLY LLP
680 Maine Avenue S.W.
Washington, DC 20024
(202) 434-5000

Attorneys for Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd.